REMARKS

Claims 1-27 remain pending in the application and are subject to restriction. The applicant respectfully traverses the requirement for restriction, and hereby elects, with traverse, the invention of Group II, claim 12-22 for prosecution. Accordingly, claims 1-11 and 23-27 are withdrawn from consideration as being directed to a non-elected invention. The applicant reserves the right to re-present these claims at a later date in this or other applications.

The applicant respectfully traverses the requirement for restriction. The action defines the three-way restriction by the following groups:

> Group I: claims 1-11 "drawn to a method of determining heparin-induced thrombocytopenia II complex, classified in class 435, subclass 2;
>
> Group II: claims 12-22 "drawn to an apparatus, classified in class 435, subclass 287.1; and
>
> Group III: claims 23-27 "drawn to kit, classified in class 424, subclass 9.1."

The application was filed with 27 claims, of which claims 1, 12 and 23 are independent claims. Claim 1 recites a method of determining heparin-induced thrombocytopenia II complex; claim 11 an apparatus of determining heparin-induced thrombocytopenia II complex; and claim 23 a kit for use with a blood hemostasis analyzer for determining heparin-induced thrombocytopenia II complex. Thus, the groups are related in that Group I claims a process and Groups II and III claim apparatus to practice the claimed process.

The basis for the restriction is that the inventions are distinct because the claimed method allegedly "can be practiced by hand through working at the laboratory with all the necessary reagents and equipments without using the apparatus and kits as claimed." This statement appears to assign to the claims, without any basis therefore existing in the claims, certain characteristics. The applicants traverse this characterization of the claims to the extent it may assign to the claims limitations not otherwise set forth or required by the

claims. The action also alleges as a basis for restriction that searching the inventions of Groups I and II, Groups I and III together would impose a serious burden on the examiner.

By imposing restriction among the three groups of claims, the U.S. Patent and Trademark Office ("PTO") makes numerous admissions that may compel it to issue at least three separate patents. Specifically, if the three-way restriction requirement is maintained, then the PTO admits:

> The Group II apparatus is patentable over a disclosure of the Group I process – utilizing the Group II apparatus – for determining heparin induced thrombocytopenia II complex, and vice versa;
>
> The Group III apparatus is patentable over a disclosure of the Group I process – utilizing the Group III apparatus – for determining heparin induced thrombocytopenia II complex, and vice versa; and
>
> The Group II apparatus is patentable over a disclosure of the Group III apparatus, and vice versa.

See, e.g., MPEP § 802.01 (8th Ed., Rev. 3, Aug. 2005). These admissions are necessary to the PTO's entry of the restriction requirement and may be relied upon by the applicant during examination of this application and future divisional applications, unless the restriction requirement is withdrawn. If the PTO is not making these admissions regarding patentability, then the restriction requirement should be withdrawn.

The restriction requirement also should be withdrawn because the restriction may present potential double patenting. According to the MPEP, the patent statute (e.g., 35 USC § 121):

> prohibits the use of a patent issuing on an application with respect to which a requirement for restriction has been made, or on an application filed as a result of such a requirement, as a reference against any divisional application, if the divisional application is filed before the issuance of the patent. The 35 U.S.C. 121 prohibition applies only where the Office has made a requirement for restriction. ... This apparent nullification of double patenting as a ground of rejection or invalidity in such cases imposes a **heavy burden** on the Office to guard against

> erroneous requirements for restrictions where the claims define essentially the same invention in different language and which, if acquiesced in, might result in the issuance of several patents for the same invention.
>
> See MPEP § 804.01 (8th Ed., Rev. 3, Aug. 2005) (emphasis added).

The applicant respectfully requests reconsideration and withdrawal of the restriction requirement in view of the foregoing admonitions.

According to the MPEP, a requirement for restriction between multiple inventions is proper only when the PTO establishes (1) that the claimed inventions are independent or distinct, and (2) there would be a serious burden on the examiner if restriction were not required:

> If the search and examination of all the claims in an application can be made without serious burden, **the examiner must examine them on the merits, even though they include claims to independent or distinct inventions.**
>
> MPEP § 803 (8th Ed., Rev. 3, Aug. 2005) (emphasis added).

The applicant acknowledges that "a serious burden on the examiner may be *prima facie* shown by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02 [(8th Ed., Rev. 3, Aug. 2005)]." MPEP § 803(II). However, in the instant case, any *prima facie* showing of serious burden is rebutted because the search of one group will include a search of another group. *Id.* (stating that a "*prima facie* showing [of serious burden] may be rebutted by appropriate showings or evidence by the applicant").

The claims of Groups I and II are concerned with and recite related subject matter; specifically in that Group I recites a method for determining heparin induced thrombocytopenia II complex while Group II claims an apparatus substantially performing the claimed method. Group III recites apparatus useful with either the process of the Group I claims or the apparatus of the Group II claims. The subject matter recited in all of the pending claims is sufficiently similar such that a complete search directed to the Group I process, the Group II apparatus and the Group III apparatus would include a search directed

to the process of Group I, the apparatus of Group II and the apparatus of Group III, and vice versa.

Because search and examination of the Groups I, II and III can be performed without serious burden on the PTO, requiring the applicant to prosecute those claims in separate patent applications would waste the time, effort, and resources of both the applicant and the PTO. Furthermore, the applicant will likely incur additional prosecution costs associated with filing multiple divisional applications and the PTO will be required to perform duplicative searches if the restriction requirement is maintained. Thus, withdrawal of the restriction requirement relative to Groups I, II and III will actually reduce the burden on the PTO and on the applicants.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

By /Anthony G. Sitko/
Anthony G. Sitko
Registration No.: 36,278
MARSHALL, GERSTEIN & BORUN
233 S. Wacker Drive, Suite 6300
Sears Tower
Chicago, Illinois 60606-6357
(312) 474-6300
Attorney for Applicant